

### REMARKS

Claims 1-49 are pending in the application. Claims 1, 6, 8-11, 17, 24-26, 28, 31, 39, and 46 have been amended herein. Claims 48 and 49 are have been added. Support for the additional claims can be found at page 7, lines 22-23 as well as in claim 1 as originally filed. No new matter has been added.

### EXAMINER INTERVIEW

Applicants thank Examiner for interview of May 9, 2008 regarding suggest amendment for the claims of the instant Application.

### OBJECTIONS

#### Objections to the Specification

The Examiner objected to the specification because it allegedly does not provide support for "about 14" in claim 24, "about 12" in claim 46 and "about 16" in claim 46. Applicants have amended claims 24 and 46 to delete the word "about". Applicants respectfully submit that this objection is overcome.

#### Objections under 37 CFR 1.75(c)

Claims 9, 24 and 31 were objected to for allegedly being in improper dependent form for failing to further limit the subject matter of a previous claim. Claims 9 and 31 have been amended to recite wherein said crystalline monoglyceride comprises 1-Glycerolmonolaurate (C12), 1-Glycerolmonomyristate (C14), or mixtures thereof and have been amended to depend from claim 1 and claim 26, respectively. Thus claims 9 and 31 further limit the claim from which they depend. Further claim 24 has been amended to delete the word "about" so that it cannot not be broader than the 16 carbon atoms recited in the claim from which claim 24 depends.

Applicants submit that the claim objections have been overcome.

### CLAIM REJECTIONS

#### Rejections under 35 U.S.C. 112, Second Paragraph

Claims 1-25 were rejected under 35 U.S.C. 112, second paragraph as being incomplete for omitting essential elements of the claims. Specifically, the Examiner alleged that claims 1

and 25 do not recite the addition of hydrogen peroxide. Applicants have amended claims 1 and 25, from which the remaining rejected claims depend, to recite that the hydrogen peroxide is added before or after cooling the solution based on the total weight of the composition.

Claims 17 and 39 are rejected as being indefinite. Specifically, the Examiner indicates that the term lipids lacks proper antecedent basis. Applicants have amended claims 17 and 39 to include an antecedent basis.

Applicants submit that claims 1-25 are definite and respectfully request that this rejection be withdrawn.

### **Rejections under 35 U.S.C. 103**

Claims 1-21, 23-43 and 45-47 are rejected under 35 U.S.C 103(a) as being unpatentable over the combined teachings of U.S. Patent No. 4,557,935 ("af Ekenstam") and WO/8703779 ("the '779 publication") in view of U.S. Patent No. 4,534,945 ("Hopkins"), U.S. Patent No. 5,078,672 ("Dougherty"), U.S. Patent No. 5,693,318 ("Burke") and S. Block, Disinfection, Sterilization and Preservation, Fourth Edition (1991) ("Block"). Specifically, the Examiner argued that af Ekenstam discloses stabilizing 0.2-5 wt % hydrogen peroxide with 20-30 wt % of hydrophilic lipid crystals of at least one of 1-monolaurin (C12) and 1-monomyrustin (C14), and that additional agents such as zinc and salicylic acid can be included. (See, Office Action at page 4). Further, the Examiner asserted that the '779 publication teaches adjusting the components such that the composition formed is a liquid instead of an ointment. The Examiner also asserted that the '779 publication also teaches adding complex forming agents such as EDTA, citric acid and different phosphonic acids. (See, Office Action at page 5). The Examiner cited Hopkins to show that it is well known that the quantity of stabilizer required decreases with increasing concentration of the hydrogen peroxide. (See, Office Action page 6). Further, Dougherty is cited by the Examiner for teaching stabilizing hydrogen peroxide of any convenient concentration with a tin (II) salt such as stannous oxalate, which can contain 0.5 wt.% oxalic acid. (See, Office Action at page 6). Moreover, the Examiner alleged that Burke teaches a skin care composition that contains the combination of 0.5-5% hydrogen peroxide, 0.5-5% salicylic acid, a surfactant and a phosphate ester stabilizer and that Block teaches that hydrogen peroxide is most active at pH 5. (See, Office Action at page 7). The Examiner argued that af Ekenstam and the '779 publication does not teach the tin salt, but that the other cited references disclose that it was well known in the art that tin compounds stabilize

hydrogen peroxide. Moreover, the Examiner argued that the pH range of the instant claims would have been obvious because "about 4.9" includes pH 5.0 which the Examiner alleged is shown to be effective by Block. Applicants traverse this rejection with respect to the claims as amended herein.

Applicants submit that there the Examiner has not established a *prima facie* case of obviousness for claims 1-21, 23-43 and 45-47 in light of the teachings of af Ekenstam and the '779 publication in view of Hopkins, Dougherty, Burke and Block. Moreover, Applicants assert that one of ordinary skill in the art would have no reasonable expectation of success for to arrive at the claimed invention based on the teachings of the references cited by the Examiner.

*No Prima Facie Case of Obviousness*

Prior art references need not teach or suggest all the claim limitations; however, Office personnel must explain why the differences between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art.<sup>1</sup> In the instant case, the Office Action fails to appreciate the differences between the prior art and the claimed invention.

Applicants submit that Block does not teach or suggest the pH range of the claims. Claims 1, 25, 26 and 47, from which claims 2-21, 23, 24, 27-43, 45 and 46 depend, have been amended to delete "about" from the pH range of the claims. Thus, the pH of 5.0 of Block does not teach or suggest the pH range of the claims. The Examiner has not explained why the difference between the claimed subject matter and the prior art is obvious, and thus, there is no proper *prima facie* case of obviousness.

*No Reasonable Expectation of Success*

Applicants submit that one of ordinary skill in the art would not have a reasonable expectation of success to arrive at the invention of claims 1-21, 23-43 and 45-47 based on the teachings of af Ekenstam and the '779 publication in view of Hopkins, Dougherty, Burke and Block. A rationale to support a conclusion that a claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary

---

<sup>1</sup> Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*, Federal Register / Vol. 72, No. 195, Page 27528 / Wednesday, October 10, 2007.

skill in the art.<sup>2</sup> Thus, a rationale for obviousness must show a reasonable expectation of success.<sup>3</sup>

Applicants submit that one of ordinary skill in the art would not have had a reasonable expectation of success in creating a stable composition of hydrogen peroxide at a pH between 3.5 and 4.9 based on the teachings of af Ekenstam and the '779 publication in view of Hopkins, Dougherty, Burke and Block. The only reference that teaches a pH close to the relevant range is Block. However, Block does not teach that pH 5.0 is an appropriate pH for long term storage of hydrogen peroxide, let alone storage according to the limitations of the instant claims.

Block teaches that hydrogen peroxide is, in certain circumstances, an effective bactericide at pH 5.0.<sup>4</sup> However, as shown in M.G. C. Baldry Journal of Applied Bacteriology 54:417-423 (1983) ("Baldry") filed with an Information Disclosure Statement herewith, this hydrogen peroxide was not stored for more than 24 hours. Table 9-4 of Block is taken from Table 1 of Baldry. In Baldry, 35% w/w hydrogen peroxide was used to create more dilute solutions used in the experiments, including those shown in Table 1.<sup>5</sup> These dilute solutions were made as needed, and were not stored for any period of time. Thus, the effectiveness of the pH shown is for the bactericidal or sporicidal activity of hydrogen peroxide, but this pH does not take into account the stability of the dilute hydrogen peroxide.

As shown in the instant specification, the prior art shows that a pH range of 2.5 to 6.5 results in 45-55% hydrogen peroxide remaining after two years.<sup>6</sup> Surprisingly, the instant specification shows that the compositions of the instant claims, with pH within the range of 3.5-4.9 have greater than 90% stability over two years.<sup>7</sup> Without the teachings of the instant specification, one of ordinary skill in the art would not have had a reasonable expectation of success in creating a stable formulation of hydrogen peroxide at the pH range of the instant claims, particularly based on the teachings of af Ekenstam and the '779 publication in view of Hopkins, Dougherty, Burke and Block.

<sup>2</sup> KSR International Co. v. Teleflex Inc., USPQ2d 1385, 1395 (2007); Sakraida v. AG Pro, Inc., 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); Anderson's-Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147, 152, 87 USPQ 303, 306 (1950).

<sup>3</sup> MPEP § 2142.03.

<sup>4</sup> See Table 9-4 of Block.

<sup>5</sup> See Baldry at page 418, left column, first and third paragraphs and right column, second paragraph.

<sup>6</sup> See the instant specification at page 3, lines 1-7.

<sup>7</sup> *Id.* at page 12, Table 3.

For the above reasons, Applicants submit that claims 1-21, 23-43 and 45-47 are non-obvious over the teachings of af Ekenstam and the '779 publication in view of Hopkins, Dougherty, Burke and Block and respectfully request that this rejection be withdrawn.

Claims 1-47 are rejected under 35 U.S.C 103(a) as being unpatentable over af Ekenstam and the '779 publication in view of Hopkins, Dougherty, Burke, Block and Derwent abstract 1999-541010 ("Derwent"). The teachings of all the references except for Derwent are discussed above. The Examiner indicates that Derwent teaches that hydrogen peroxide, salicylic acid and glycerol are known to be used together for dermatological purposes. (*See*, Office Action at page 11). Applicants traverse.

For the reasons articulated above, Applicants submit that a *prima facie* case of obviousness has not been established over claims 1-47 in light of the teachings of af Ekenstam and the '779 publication in view of Hopkins, Dougherty, Burke, Block and Derwent. Moreover, one of ordinary skill in the art would not have a reasonable expectation of success for the invention of claims 1-47 based on the teachings of af Ekenstam and the '779 publication in view of Hopkins, Dougherty, Burke, Block and Derwent.

For the above reasons, Applicants submit that claims 1-47 are non-obvious over the teachings of af Ekenstam and the '779 publication in view of Hopkins, Dougherty, Burke, Block and Derwent and respectfully request that this rejection be withdrawn.

### CONCLUSION

On the basis of the foregoing amendment and remarks, Applicants respectfully submit that the pending claims are in condition for allowance and a Notice of Allowance for the pending claims is respectfully requested. If there are any questions regarding this application that can be handled in a phone conference with Applicants' Attorneys, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

Reg. No. 58,032

Bo:

Naomi S. Biswas, Reg. No. 38,384  
Attorney for Applicants  
c/o MINTZ LEVIN  
Telephone: (617) 542-6000  
Facsimile: (617) 542-2241  
**Customer Number 30623**

Dated: November 14, 2008